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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,548	07/11/2003	Ashish Anilbhai Patel	G-33280P1	5169

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,548	PATEL ET AL.	
	Examiner	Art Unit	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/11/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-21 ARE PRESENTED FOR EXAMINATION

Applicants' Information Disclosure Statement filed July 11, 2003 has been received and entered into the application. As reflected by the attached, completed copies of form PTO-1449 (2 pages), the cited references have been considered.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al. (U.S. Patent No. 4,743,450, cited by Applicants) in view of Vivilecchia et al. (U.S. Patent No. 6,300,361, cited by Applicants), Handbook of Pharmaceutical Excipients ("the Handbook", cited by the Examiner), Applicants' acknowledgment at page 4, third full paragraph – page 5, second

full paragraph of the present specification and Remington's Pharmaceutical Sciences ("Remington's", cited by the Examiner).

Harris et al. teach pharmaceutical compositions that are stable from degradation by (1) cyclization via internal nucleophilic attack to form substituted diketopiperazines, (2) hydrolysis of the side-chain ester group and (3) oxidation to from products having unwanted coloration (col. 1, lines 5-13 and 25-35).

The composition comprises about 1-70% (based on the total composition weight) of an angiotensin converting enzyme (ACE) inhibitor which may be any of a group of well-known compounds which have antihypertensive properties and of which enalapril, quinapril or indolapril are highlighted (col. 2, lines 8-11, 32-34 and 38-41); from about 1-90% (based on the total composition weight) of a stabilizer which is an inorganic salt of metals of Groups I and II of the Periodic Table, including magnesium calcium and sodium, the anionic portion of which is preferably a carbonate (col. 3, lines 30-39); and an excipient which may be a modified cellulose disintegrant which will generally comprise about 1% to about 15% (based on the total composition weight) of the composition (col. 4, lines 3-10).

Harris et al. further teach that the composition may take the form of various pharmaceutical forms including tablets, caplets and capsules.

The differences between the above and the claimed subject matter lie in that Harris et al. fail to highlight:

(1) Each of the presently claimed ACE inhibitors;

(2) each of the cationic portions of the carbonate stabilizer;

(3) the presence of hydroxypropyl cellulose and the specific types claimed;

(4) the specifically claimed ingredient proportions (each of the above as in present claims 1-20); and

(5) the claimed manufacturing process (present claim 21).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(1) As noted above, Harris et al. teaches that any antihypertensive ACE inhibitor may be employed. Vivilecchia et al. teach the remainder of the presently claimed ACE inhibitors not specifically taught by Harris et al. as being known antihypertensive ACE inhibitors (col. 5, lines 58-64) and the skilled artisan would have been motivated to employ such ACE inhibitors because Harris et al. specifically teaches that any antihypertensive ACE inhibitor may be employed.

(2) The presently claimed cation portions of claimed carbonate ingredient were well known to be metals of Groups I and II of the Periodic Table.

(3) Hydroxypropyl cellulose, by virtue of the hydroxypropyl moieties would have been recognized as being a modified cellulose and the Handbook teaches that hydroxypropyl cellulose was well known in the art to be a disintegrant (see page 137, paragraph "18"). Also, Applicants have acknowledged that the presently claimed hydroxypropyl cellulose types were known and available. The selection of any particular type of hydroxypropyl cellulose from those known would have been a matter well within the purview of the skilled artisan.

(4) The reference teaches weight percentages for the ACE inhibitor and the carbonate component that are encompassed by the present claims. While present claim 19 requires a proportion of hydroxypropyl cellulose of "about 30 wt. % to about 40 wt. %" and Harris et al. highlights a range of from about 1% to about 15%, the claimed proportions would have nevertheless been obvious because Harris et al. further teach that "[t]he percentages in which excipients are used are not critical. In general, their quantities will be consistent with the amount given above for the drug, stabilizer and lubricant components, i.e., they make up the remainder of the composition". Thus, the proportion of ingredients is not limited to the particular percentages highlighted by the patentees and the determination of the optimum proportion of ingredients to employ would have been a matter well within the purview of the skilled artisan.

(5) Harris et al. teaches that a wet granulation process is the preferred process for manufacturing the compositions (see col. 4, lines 26-28). Remington's teaches that a wet granulation process includes those steps claimed by applicants, i.e., mixing ingredients to form a premix; forming a wet granulation by adding a solvent; drying the wet granulation; milling the resulting dried granulation; and then forming a composition therefrom (see page 1560, column 2, under the heading "Wet-Granulation Method" – page 1563).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

May 24, 2004